

FEB 12 2002

510(k) Summary of Safety and Effectiveness

Date Prepared: June 30, 2001

Name of Contact Person: Ralph J. Flatau

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K 012490

Device trade name: Orion Fluoroscopic Imaging System

Common name: Digital Radiography System

Classification Name: Image intensified fluoroscopic X-ray system

Device Description:

The Orion fluoroscopic imaging system allows the use of digital imaging to conventional X-ray system used in the general fluoroscopy, interventional fluoroscopy, angiography and cardiac imaging areas. The system works by installing a CCD camera on the output of the image intensifier and digitizing the video output of the image intensifier. The digital image can then be displayed on the monitor, it can be stored to disk, or sent to an external device such as a laser imager or a DICOM network. The image can also be processed, including brightness and contrast, edge enhancement, zoom, and subtraction.

Intended Use:

The InfiMed Orion Fluoroscopic imaging system is a high resolution, digital imaging system designed for digital videography. It is intended to replace conventional film techniques in multipurpose or dedicated applications where general fluoroscopy, interventional fluoroscopy or angiography or cardiac imaging procedures are performed.

The Orion system allows the operator to view and enhance 1000 line fluoroscopy. High resolution digital spot images (1024x1024) may be acquired at single or rapid acquisition rates. Images may be viewed and enhanced enabling the operator to bring out diagnostic details difficult or impossible to see using conventional imaging techniques.

The Orion system enables the operator to hardcopy image with a laser printer or send images over a network. The major system components include: a fluoroscopic TV camera, monitors, and an image processor.

Conclusions drawn from comparison:

The Orion fluoroscopic imaging system can be considered to be substantially equivalent to the InfiMed GoldOne Fluoroscopic System (510(k)-K963037) and the InfiMed FC2000 Fluoroscopic System (510(k) - K911454A). Virtually all of the features offered by either of the predicate devices are offered by the Orion product. There are a number of additional features that the Orion product offers, most of which are possible because of the increased power of the system. Some of these features require additional interfaces to acquire the data. In addition, to facilitate patient safety, some key interfaces have been changed from wires to fiber optics.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 12 2002

Mr. Brian N. Killoran
Quality Assurance Manager
InfiMed, Inc.®
121 Metropolitan Drive
LIVERPOOL NY 13088

Re: K012490
Trade/Device Name: Orion Digital Imaging System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic
x-ray system
Regulatory Class: II
Product Code: 90 JAA
Dated: December 12, 2001
Received: December 21, 2001

Dear Mr. Killoran:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

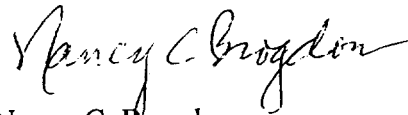
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number K012490

Unknown at this time.

Device Name

Orion Fluoroscopic Imaging System.

Indications for Use

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The Orion system enables the operator to hardcopy image with a laser printer or send images over a network for longer term storage. The major system components include: a fluoroscopic TV camera, monitors, and an image processor.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (DOE)

Prescription Use /

Or

Over the counter Use

Per 21 CFR 801.109

(Optional format 1-2-96)

Nancy C. Brogdon
(Division Sign-Off)

Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K012490